In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

(Filed: September 29, 2005)

AUTISM MASTER FILE

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER OR A SIMILAR NEURODEVELOPMENTAL DISORDER

VARIOUS PETITIONERS,

V.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

AUTISM UPDATE--SEPTEMBER 29, 2005

This Update describes a number of recent developments in the Omnibus Autism Proceeding that have occurred since my last Update, dated June 27, 2005. I note that counsel for both parties and I have continued to work diligently on the Proceeding during that time period. Unrecorded telephonic status conferences were held on July 15, August 4, August 11, and September 22, 2005.

A. Number of cases

At this time, more than 4,900 petitions in autism cases have been filed, and more than 4,600 remain pending, stayed (at the petitioners' own requests) until the conclusion of the Omnibus Autism Proceeding.² Additional petitions continue to be filed regularly.

¹Counsel participating in those conferences included Thomas Powers and Ghada Anis for petitioners, along with Vincent Matanoski and Mark Raby for respondent.

²Many of the cases that are no longer pending were voluntarily dismissed or withdrawn by the petitioners; in most of those cases, the dismissal was due to the fact that, inadvertently, a second petition had been filed pertaining to the same autistic child. A number of other cases have been dismissed by me because they were not timely filed.

B. Discovery

As indicated in my previous Autism Updates, a tremendous amount of work has been done by counsel for both parties concerning the petitioners' extensive discovery requests. I will not reiterate developments covered in my previous updates, but I will summarize below our progress, and note certain new developments in the discovery area.

1. General progress concerning petitioners' discovery requests

As reported previously, petitioners have made two extensive discovery requests for materials from government files, and as a result many thousands of pages of material have been copied from government files and supplied to petitioners. At this point, all of the petitioners' discovery requests have been resolved, except for the ongoing production discussed at point 2 below and the ongoing procedures discussed at point 3 below. (By my informal count, the total number of pages of documents provided by respondent to the petitioners (not counting the material available via website) now approximates 197,000 pages.)

2. The vaccine license application files

One category of documents requested, pursuant to petitioners' original Requests for Production Nos. 10 and 12, involves vaccine license applications. In this area, efforts to produce material have proceeded slowly, as detailed in my previous Autism Updates, but the process of production of that material continues to move forward, and is now very near completion. In recent weeks, respondent submitted to the Petitioners' Steering Committee (hereinafter "the Committee") portions of the Food and Drug Administration (FDA) files that pertain to the Aventis tetanus vaccine (832 pp.); the Wyeth/Praxis DPT vaccine (200 pp.); the Wyeth/Praxis DT vaccine (78 pp.); the Lederle DTP vaccine (9 pp.); the Lederle tetanus vaccine (12 pp.); the GlaxoSmithKline hepatitis B vaccine (28 pp.); the Aventis DT vaccine (44 pp.); and the Wyeth/Praxis tetanus vaccine (13 pp.). Prior to that, other portions of the files for most of those vaccines were submitted, and files for the following additional vaccines were submitted: the Merck MMR combined vaccine, the Merck mumps vaccine, the Merck measles vaccine, the Merck HIB conjugate vaccine, the Merck rubella vaccine, the Merck hepatitis B vaccine, the Baxter/North American Healthcare DTaP vaccine, the Aventis HIB conjugate vaccine, the Aventis DTaP vaccine, the Aventis DTP vaccine, the Wyeth/Lederle DTaP vaccine, the Lederle DT vaccine, the Lederle HIB conjugate vaccine, and the Lederle DPT/HIB conjugate vaccine.

Certain additional files with respect to three vaccines are continuing to move through the final stages toward disclosure. The parties anticipate that within a few weeks, this process will be complete.³

3. Discovery pursuant to resolution of "motion to compel"

In the Update of April 28, 2005, I described the recent resolution of the petitioners' "motion to compel production" concerning petitioners' second round of requested government discovery. The parties are now proceeding with the discovery procedures described.

C. Judicial Conference and "in-person" autism status conference

As I have previously noted on the Autism Master File webpage, this court is hosting its anual Judicial Conference on November 3 and 4, 2005, in Philadelphia. In my filings posted on the Autism page of this court's website on August 10 and September 12, 2005, I set forth details concerning several events taking place at that Judicial Conference which are of particular relevance to attorneys who have pending Vaccine Act cases involving Autism claims. Those events include an "in-person" status conference in the Omnibus Autism Proceeding. All attorneys with such cases are invited to attend--see my filings noted above for details.

D. Ruling concerning issue of time for filing expert reports

Recently, the Committee filed a motion seeking more time in which to file the expert reports on petitioners' behalf in the Omnibus Autism Proceeding. The Committee requested that the due date for its expert reports be extended until late 2006. The respondent filed an opposition to the request. (Both filings are posted on the Autism page on this court's website.) I filed a written ruling, addressing the request, on August 11, 2005.

In that ruling, I concluded that the legal argument raised by respondent was not meritorious. I deferred indefinitely the due date for the petitioners' expert reports. However, I provided that by

³I note that while the Committee's discovery *requests* have been filed into the Autism Master File, the respondent's discovery *responses* have been filed into the file of an individual autism case, *Taylor v. HHS*, No. 02-699V. The latter file is available to autism petitioners and their counsel, via special procedures set up by the Committee, but not to the general public, as mandated by the Vaccine Act. (See discussion in my Autism Update filed on June 23, 2004, pp. 4-6.)

January 31, 2006, petitioners must designate who their experts will be, and must also file at that time a statement from an *expert*, giving the *expert's* view as to whether it is necessary to wait until late 2006 to file the expert reports. If such petitioners' *expert* states the opinion that it is necessary to wait until late 2006, and adequately explains such opinion, then at that time I may elect to defer the due date until late 2006.

E. Future proceedings

As indicated in my previous Updates, the general plan for the Omnibus Autism Proceeding is that once the Committee is done with its discovery process, both sides will file expert reports, and then I will conduct an evidentiary hearing concerning the general causation issue. As indicated above, while the discovery process is now nearing completion, the Committee wishes to delay the filing of expert reports for an additional time period, in anticipation of the completion of a number of studies that may be relevant to the general causation issue. As also indicated, I will continue to monitor this process carefully, in order to give the Committee the time that it reasonably needs, but also move the Proceeding to completion at the earliest date that is reasonable under all the circumstances.⁴

The next status conference in the Omnibus Autism Proceeding is scheduled for October 25, 2005.

George L. Hastings,

Special Master

⁴I note, as I have in the past, that it is up to each individual petitioner to determine whether to defer proceedings concerning his or her own case pending the completion of the Omnibus Autism Proceeding. If an individual petitioner has proof of causation in his own case that he wishes to put before a special master at any time, that petitioner will be afforded a prompt hearing. Or, a petitioner whose petition has been pending for 240 days has the option of electing to withdraw from the Program under the procedure of 42 U.S.C. § 300aa-21(b), during the 30-day period after I issue the notice required under 42 U.S.C. § 300aa-12(g).